# STERILIZATION AND DISINFECTION: OBJECTIVES AND PERSPECTIVES

**Erasmus Wilson Demonstration at the Royal College of Surgeons of England**
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**by**

**J. C. Kelsey, M.A., M.D., F.C.Path., Dip.Bact.**
**Director, Central Public Health Laboratory, Colindale Avenue, London, N.W.9**

THE INTEREST SHOWN by hospital staff, be they surgeons, pathologists or administrators, in matters of sterilization and disinfection varies between the negligible and the obsessional. As my title indicates I hope not only to discuss the basic principles of sterilization and disinfection as applied to surgery but also to indicate their relative priorities and those matters with which the individual surgeon should concern himself personally.

The first question that must be asked is why it should be necessary to kill microbes. They are ubiquitous, the vast majority do no harm to anyone and many contribute greatly to the well-being of mankind; some are concerned with the maturing of cheese and other foodstuffs, many in the soil and elsewhere play a vital rôle in dealing with unwanted organic matter and operating the nitrogen cycle; moreover there is increasing evidence that even within our own gut most of the microbes contribute positively either by competing with pathogens or by contributing substances which are of value to their human hosts. The doctrine that the only good germ is a dead one cannot stand up to serious investigation; it is therefore important to consider those situations in which microbes must be excluded; there are probably five such situations:

1. *Dangerous microbes*—not allowed anywhere. Such organisms as the typhoid bacillus and the virus of smallpox can cause serious disease in very small numbers and must be excluded by any means possible from the human environment.

2. *Critical sites*—no microbes allowed. This is the category that includes surgical intervention. Although many of the body cavities normally contain a resident bacterial flora and even those tissues which are normally sterile are often able to eliminate invading bacteria with remarkable efficiency, it has been an axiom since the days of Lister, well supported by subsequent experience, that all microbes should be excluded from body sites which are normally sterile. This is particularly important in joint cavities and in the meninges, where resistance to microbial infection is low and serious sepsis can be caused even by lowly organisms that are not normally pathogenic. Even so it is probable that few operations take place in which the occasional microbe does not find its way into a forbidden site, so that the most elaborate aseptic precautions must still be regarded as being supported by the body's natural defences. The

general policy of conducting most, if not all, surgery under aseptic conditions is one that depends on a policy decision based on general principles and experience rather than on the results of experiment or quantitative clinical trial. The development of immunosuppressive drugs has greatly increased the hazard of surgical sepsis and it is best to regard all patients for whom operation is necessary as being highly susceptible to infection.

3. *Cultural purity*—no outsiders allowed. This situation does not concern the surgeon but is very important for the clinical bacteriologist who must work with sterile culture media to ensure that anything grown comes from the inoculum and has not been introduced during the process of culture. It is important in such industrial operations as brewing and antibiotic manufacture.

4. *Spoilage*—no vandals allowed. Non-pathogenic organisms introduced into foodstuffs may spoil the flavour without necessarily making the product dangerous.

5. *Special and research.* Two such situations are the use of germ-free animals for various research purposes and the space programme. In the latter, elaborate precautions are taken to ensure that other planets are not contaminated by terrestrial germs and that extra-terrestrial germs, which could prove very dangerous to this planet, are not introduced to earth from outer space.

These are the situations from which microbes must be excluded; it is important to appreciate that such microbes may vary greatly in their resistance to physical and chemical treatment. Mycobacteria, such as those that cause tuberculosis, are frequently more resistant than other vegetative bacteria; bacterial spores are usually more resistant still. Respiratory viruses are more easy to kill by heat than enteroviruses and the pox viruses less easy. The agent, or agents, that cause hepatitis appears to be very resistant, but until it can be identified and studied it is not possible to make very definite statements about this. The resistance of viruses to inactivation by ionizing radiation seems to vary inversely as their size, and the recent literature contains references to agents, such as that thought to cause ' scrapie ', which are very resistant to heat and other disinfecting processes and have not yet been assigned to any microbiological class. Fungi and protozoa are not in general very resistant except when they form spores or cysts. Thus when discussing sterilization and disinfection it must be made clear what groups of organisms are referred to, as procedures adequate to kill simple vegetative organisms, such as pseudomonads or coliforms, may be quite ineffective against bacterial spores or certain viruses.

## SOME DEFINITIONS

Before we consider what processes are available for sterilization and disinfection it is necessary to define some terms used in this field.

1. *Sterilization:* this term implies the removal or destruction of all microbes, including resistant spores, viruses and other harmful agents.

2. *Disinfection:* this is a less precise term meaning to free from infection and by implication make safe to handle. It usually means to destroy harmful microbes, but by custom it does not usually imply the destruction of bacterial spores. Normally its use has been confined to the treatment of inanimate objects, but this usage is now being extended to include living tissues.

3. *Antisepsis:* this is an imprecise and by now somewhat archaic expression meaning to oppose sepsis and decay by killing microbes or inhibiting their growth. In the past it has been used for the disinfection of skin and mucous membranes, but because of its lack of precision this is now called skin disinfection. The term antisepsis is best avoided.

4. *Sanitization:* this is an ugly word of transatlantic origin which is nonetheless very useful; it means the reduction of the number of bacteria to some acceptably low level. It was originally introduced for catering utensils but is increasingly being used in other contexts.

The most precise of these definitions is sterility. Theoretically this is an absolute concept but practical sterilization must in fact be relative; the apparent efficacy of any method depends on the rigour of the tests applied. Positive bacterial cultures have been obtained after incubation periods of over a year. In practice shorter incubation periods must obviously be accepted. Viruses are not now sought in routine sterility tests but they may need to be considered in the future. Only a red-hot poker or the immediate proximity of a radio-active source can in fact be guaranteed sterile in any absolute sense. Organisms can be recovered from soil and from certain manufacturing processes which are known to survive sterilizing procedures prescribed in such official documents as pharmacopoeias and government specifications. This does not cause the alarm that might be imagined, because there are many years of entirely satisfactory experience with these procedures and there is no evidence that the organisms concerned have ever been pathogenic for man. Surgeons can be confident of the safety of the materials they use if they ensure that they have been subjected to one of the officially approved sterilization processes. It is possible that one day the ambiguous and philosophically meaningless expression ' sterile ' may be replaced by a new term merely implying ' subjected to a process which everybody agrees is perfectly safe '.

## THE METHODS AVAILABLE

The methods available for sterilization and disinfection are as follows:

**Physical:** *Heat*—dry (hot air).
—moist (steam).
*Irradiation*—gamma rays—e.g. Cobalt-60.
—beta particles—e.g. linear accelerator.

**Chemical:** *Liquid ' disinfectants '*—many and various.
*Gaseous sterilizing agents*—e.g. ethylene oxide.

Of these, dry and moist heat are established methods; the place of irradiation and gaseous sterilization in hospitals is not yet defined. Liquid disinfectants are hard to test, uncertain in practice and most of them cannot be relied upon to achieve sterility.

**Test systems**

These methods need to be tested regularly to ensure that the right conditions have been applied to every part of the load to be treated. A number of test systems can be used appropriate to various sterilizing or disinfecting procedures. They are as follows:

**Physical measurements:** These include thermocouples for checking the temperature achieved in wet and dry heat sterilization and radiometers for checking the dose of irradiation applied.

**Chemical indicators:** In the U.K. the most frequently used are Browne's tubes. These are small glass tubes containing a fluid which changes colour according to time and temperature when they are heated; separate tubes are available for wet and dry heat. There are also radio-sensitive dyes which are used to give a qualitative indication that radiation has been applied rather than a quantitative indication of the dose.

**Bacterial spore preparations:** These include preparations of *Clostridium tetani* for dry heat, *Bacillus stearothermophilus* for wet heat, *Bacillus pumulus* for irradiation and a pigmented strain of *Bacillus subtilis* (*B. globigii*) for use with ethylene oxide.

In general, physical or chemical methods are to be preferred, as they are, when properly used, reliable and informative. Chemical indicators are of great value for routine use. Thermocouples are delicate and difficult to use and spore preparations are hard to make, harder to standardize, difficult to interpret and slow to give a result.

## DRY HEAT STERILIZATION

Dry heat kills microbes by oxidation; extreme degrees are in fact incineration. The method is in principle simple and sealed containers can be used, which is an advantage compared with the use of steam. A relatively long exposure time is needed to kill all spores. Current recommendations are as follows:

160° C. for 45 minutes
170° C. for 18 minutes
180° C. for 7½ minutes
190° C. for 1½ minutes.

The U.S.A. space programme uses long periods at comparatively low temperatures (e.g. up to 25 hours at 130° C. or 60 hours at 120° C.) and this may well have applications in surgical sterilization.

Heat penetrates poorly under the conditions of hot air sterilization, and special apparatus and careful techniques are needed to ensure that all parts of the load have been held at the required temperature for an adequate time. It has been shown that the conventional hot-air ovens are unsafe unless they are provided with a fan to distribute the heat, and even then the loading is critical. A British Standard Specification describes such ovens and methods of testing them.

In large syringe services conveyor ovens are used. The load is mechanically conveyed on a moving belt through a tunnel heated electrically or by gas; the process is automatically controlled by thermostats. The run is usually short and lasts about 30 minutes, compared with an hour or more in a fan oven.

Hot air is the method of choice for sterilizing syringes and is used by some hospitals for metal instruments: now that modern steam techniques have been shown not to damage cutting edges this use is likely to decline. Some ophthalmic surgeons consider that dry heat is less damaging to sharp instruments than is steam. Others disagree, and in the absence of any objective test for sharpness this matter cannot easily be settled. It is possible that damage is caused not by heat in any form but by mechanical trauma, preventable by sterilizing the instruments in racks.

Fan ovens are flexible in their uses though relatively slow; conveyor ovens, though more rapid, are less flexible and difficult to adjust for mixed loads. They are most useful in large syringe services for a large steady output of standard items.

In checking the efficacy of dry heat sterilization thermocouples may be used in the design and evaluation of apparatus but chemical indicators are of particular value in ensuring that the right time and the right temperature have been achieved. Over many years the use of Browne's tubes (No. 3 for fan ovens operating at 160° C. and No. 4 for conveyor ovens operating at 180° C.) have been found to be reliable. The tube should be inserted in the middle of a representative load and if necessary inserted inside a typical item such as a glass syringe. If the process is satisfactory all the tubes will show a green colour when removed from the oven.

## WET HEAT STERILIZATION

Moist heat kills microbes, not by oxidation, but by the denaturation of vital proteins, much as boiling denatures egg albumen. This is a more rapid process so that exposure times can be relatively short. The times recommended by the Medical Research Council for sterilization by exposure to steam are:

121° C. for 15 minutes
126° C. for 10 minutes
134° C. for 3 minutes
At 150° C. sterilization is virtually instantaneous.

These exposures should ensure surgical sterility. For certain purposes lesser degrees of heat treatment may be considered adequate. Reports of urinary infection by spore-bearing organisms are exceedingly rare and it is therefore not unreasonable, as an interim measure, to pasteurize such cystoscopes as will not withstand autoclaving by immersing them in hot water at 75° C. for 10 minutes. Boiling is scarcely more effective than pasteurization, it is difficult to control and creates embarrassing clouds of steam. The method has little to recommend it and it is gratifying to find it being progressively eliminated from British hospitals.

Sterilization by steam under pressure, when properly conducted, is certain and quick. It is important to realize that the increased pressure serves only to raise the operating temperature and by itself contributes nothing to the sterilizing process. Steam is a gas which readily condenses on cold surfaces to form water, with the release of latent heat; it can rapidly penetrate fabrics or other porous materials and raise their temperature. If penetration is to take place care must be taken in wrapping and loading; for steam sterilization closed impervious containers, which are satisfactory for hot air sterilization, cannot be used.

The main technical problem in using steam as a sterilizing agent is to remove air from the vessel and from the load. This is necessary for two reasons: a mixture of air and steam has a lower temperature than pure steam at the same pressure, and residual air tends to form over the surface of the load a thin but highly insulating film which retards heat transfer. Air is more dense than steam; if packing and loading are arranged to permit a vertical outflow of air, and if enough time is allowed, satisfactory elimination of air can be achieved by the simple process of downwards displacement. The displaced air must be removed from the bottom of the system by a ' bleeder valve ' or a steam trap.

Steam sterilization also must be checked by appropriate test methods. For the downward displacement techniques just described thermocouples may be valuable in evaluating new equipment, but for day-to-day working the accuracy of the instruments should be checked, together with the achievement of the correct temperature as registered by a thermometer placed in the chamber drain as this represents the coolest part of the sterilizing system. For checking the sterilization of individual items and of particular loads Browne's tubes are again of great value. The No. 1 tube should be used for sterilization up to 125° C. and the No. 2 tube for sterilization at higher temperatures. For reasons previously given there are few indications for using bacterial spore preparations.

The downward displacement technique is used for unwrapped instruments and bowls and until a few years ago it was used also for packaged goods, such as dressings and surgical drapes. The method of choice for porous loads is now the high-vacuum sterilizer. Here downward displacement is substantially reinforced by removing most of the air from

the load by a pre-vacuum stage before steam is admitted. If this is successfully done steam penetration is virtually instantaneous and no time need be allowed for it. When this process is combined with sterilization at high temperatures (134° C.) only a short exposure period of 3–4 minutes need be used and this does not damage most goods. This means that the entire sterilizing cycle can be over in well under 30 minutes. Most modern dressing sterilizers of the sort used in C.S.S.D.'s are of this high pre-vacuum type. Because of the complexity of the cycle and the fact that it is invalidated by even small variations from the correct time and temperature relations or by failure to eliminate all traces of air, such sterilizers are entirely automatic in operation. Furthermore, the current British Standard Specification requires the use of automatic monitoring devices which do not allow the cycle to proceed to completion unless all the necessary conditions have been achieved. The successful operation of such sterilizers may be checked by inserting in the load Browne's tubes No. 2 appropriate to the high temperature used. Because of the importance of eliminating all traces of air a special test, the Bowie-Dick test, is commonly used for checking such sterilizers. In this test a cross of self-adhesive tape bearing heat sensitive dye is fixed to a square of paper. This is inserted in the middle of a pile of standard towels stacked in a standard manner to form a cube of side approximately 12 inches. If all the air has been eliminated there will be a uniform colour change in every part of the tape cross. If some air remains at the end of the pre-vacuum stage it will be trapped in the middle of the test pack to form a bubble, the centre of which will be at a lower temperature than the surrounding steam. This will be shown by a less intense colour change in the middle of the cross. This test is dependent on the most meticulous attention to detail and can be defeated by using the wrong sort of tape or by extending the exposure to steam beyond the prescribed time. Experience has shown that the worst situation is when a single small package is sterilized in a large chamber. This is because all the air left in the steam will be trapped in the porous material available. If the chamber is full this air will be dissipated between the packages and will not be so easily detected.

*Sterile Water.* In the past sterile water for use in operating rooms has been supplied by various types of tank sterilizer either individually situated in operating rooms or situated centrally with a common supply system. Experiment has shown that these are unreliable in that they become contaminated by bacteria suddenly and unpredictably without any apparent change in the water used. For this reason sterile water is best supplied in separate sterilized bottles processed in a special sterilizer which may be provided with a rapid cooling device if large quantities are being prepared, for example in a pharmacy or in a C.S.S.D. For special purposes such as G.U. or gynaecological surgery a continuous supply of reasonably safe water can be provided by the use of a filter or an

ultraviolet device. These require regular maintenance and careful monitoring and should not be installed without taking the advice of a bacteriologist.

## THE TREATMENT OF HEAT-SENSITIVE MATERIALS

The techniques so far described can damage heat-sensitive materials for which other and less well-established methods are available, some of which will now be described. Whenever possible equipment should be so designed that conventional methods of sterilization should be used.

*Ethylene oxide:* Ethylene oxide gas ($C_2H_4O$) has been widely used, especially in the U.S.A., to sterilize heat-sensitive materials such as plastics, both commercially and in hospital C.S.S.D.'s. It has excellent powers of penetration, most materials are undamaged, it is active against all microbes including viruses and bacterial spores, and low temperatures can be used. The gas is toxic and inflammable and conditions of concentration, temperature and humidity must be carefully controlled. Special apparatus is normally used, except on the laboratory scale. This apparatus is complex and costly and, because so many factors need to be considered if sterilization is to be achieved with any degree of confidence, it should only be used under skilled bacteriological supervision. This probably limits its use to larger establishments and to commercial production plants. The increasing use of resistant plastics and of irradiated disposable items will probably make its routine use in hospitals unnecessary.

*Irradiation:* Ionizing radiations are increasingly being used for sterilization. The most usual techniques employ gamma-rays from a radioactive source, for example cobalt-60, or beta-particles from a linear accelerator. Good penetration can be obtained and closed packs can be used. There is no residual radio-activity but some materials, such as glass, may be damaged. The dose needed to achieve sterility has not yet been finally agreed, but 2.5 megarads are generally considered adequate for clean articles. Because of the need for expensive, bulky and complex apparatus and for skilled supervision, it is unlikely that irradiation will be used in small hospitals; it will probably be centralized in large establishments or in factories supplying sterile disposable goods for hospital use.

A routine irradiation service for hospitals is available from Isotope Research Division (A.E.R.E.), Wantage Research Laboratory, Berkshire.

*Formaldehyde vapour:* This has very poor powers of penetration and is difficult to control; it cannot be relied upon to sterilize instruments or catheters, and should be used, if at all, only for the terminal disinfection of rooms.

*Low temperature steam:* This technique is still being developed but is already showing promise. It is similar to a high-vacuum sterilization cycle, but the steam admitted after the pre-vacuum stage is only allowed to reach subatmospheric pressure, so that the holding temperature is

70° to 80° C. Rapid penetration can be obtained into fabrics; blankets, plastics, rubberware, endoscopes or electrical apparatus can be disinfected within 10 to 15 minutes without damage. If formaldehyde is added, substantial numbers of spores can be killed in one to three hours and the process may be regarded as achieving sterilization rather than disinfection.

## LIQUID CHEMICAL DISINFECTANTS

The surgeon is likely to meet these in two contexts, for skin preparation or surgical scrubbing and for the disinfection of operating rooms. In the U.K., at least, the work of Lowbury *et al.* (1963, 1964) has defined the rôle, techniques and limitations of agents designed for disinfecting the skin of pre-operative sites and of the hands of the surgical team. Although liquid disinfectants may be needed for cleaning up gross contamination of floors, walls or fittings, more emphasis is now placed on thorough and regular cleaning to good domestic standards. Fogging with antimicrobial aerosols has not been completely evaluated, but its value is likely to be limited to such situations as recovery rooms where there may be a rapid throughput of high-risk patients with inadequate time for cleaning between each. It is certainly no substitute for a good cleaning routine.

## CONCLUSION

This account of the aims of sterilization and disinfection and the methods whereby these aims may be achieved will have made it clear that there are many technicalities with which the practising surgeon cannot be expected to concern himself. It is also important to remember that when unexplained surgical sepsis has occurred to such an extent that outside investigation has proved necessary it is very seldom that the blame can be attributed clearly or even at all to some abstruse and technical fault in sterilizing procedures. Most commonly no single cause is found but rather a number of possible sources of trouble; where the cause of such disasters is clearly discovered it is usually due to some simple failure in communication or a failure to define responsibility. The important question to be asked by the surgeon is probably not so much how was this object sterilized but by whom. It may therefore be helpful to conclude by suggesting certain practical steps that can be taken by the surgeon if he wants to minimize surgical sepsis or anxiety about it.

1. He should be generally familiar in broad outline with the various techniques available for sterilization and disinfection so that he will not ask the impossible and will understand when difficulties are explained and be prepared to discuss alternative arrangements.

2. He will make himself personally familiar with the bacteriologist or pathologist in his hospital, preferably in the context of a control of infection committee at which techniques can be discussed and difficulties resolved.

3. When the surgeon is asked for an opinion about new sterilizing

equipment he will insist that it is only purchased by a responsible officer who is prepared to take advice. British Standards exist for hot air ovens and for autoclaves of all types and in England and Wales the Scientific and Technical Services Branch of the Department of Health and Social Security (or in Scotland the Home and Health Department) is always ready to advise over detail.

4. When purchasing (or designing) new surgical equipment he will ask how it can be sterilized before purchasing it. In this way he may prevent much trouble in attempting to sterilize the unsterilizable.

5. In so far as this is possible he will try to agree with his colleagues on as great a uniformity of equipment and apparatus as possible, so that the sterilizing procedures may be simple and clearly understood by the staff who have to carry them out. It is when different types of similar equipment have to be treated in very different ways that confusion, and not infrequently lack of sterility, may arise.

Finally, no matter how perfect the sterilizing equipment or the control of those who use it, the prevention of hospital sepsis will ultimately depend on constant attention by a large number of persons to a great many details, of which sterilizing procedures will be only one. With an orchestra of such a size the choice of conductor is of paramount importance. If the surgeon uses his influence to ensure that his hospital has an active, representative and credible control of infection committee and a control of infection officer whose responsibilities are clearly defined he will have achieved much; generations of patients and junior staff will (or at least should) rise up to bless his name.

## SUGGESTIONS FOR FURTHER READING

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